

REMARKS**Interview request**

Applicants respectfully request a telephonic interview after the Examiner has reviewed the instant response and amendment. Applicants request the Examiner call Applicants' representative, as noted below.

Status of the Claims*Pending claims*

Claims 1, 2, 4 to 9, and 14 to 55 are pending.

Claims only objected to

Applicants thank the Examiner for finding that claims 19, 20, 23 and 31 would be allowable if rewritten in independent form.

Outstanding Rejections

Claim 53 is rejected under 35 U.S.C. §101 as alleged being drawn to non-statutory subject matter. Claims 1, 2, 4 to 9, and 14 to 55 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement of section 112, first paragraph. The rejection of claims 27 to 30 and claims 40 to 43, under 35 U.S.C. §112, first paragraph, written description requirement, is maintained. Claim 36 is rejected under 35 U.S.C. §101, as allegedly claiming the same invention as that of claim 11 of USPN 5,789,228. Claims 2, 4, 5 to 9, 14, 32 to 43 and 53, stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting.

Applicants respectfully traverse all outstanding objections to the specification and rejection of the claims.

Support for the claim amendments

The specification sets forth an extensive description of the invention in the new and amended claims. For example, support for claims drawn to probes capable of identifying or isolating nucleic acids encoding a polypeptide having endoglucanase or cellulase activity can be

found, inter alia, on page 8, lines 9 to 28; page 9, lines 19 to 23; the paragraph spanning pages 13 to 14; page 20, lines 15 to 17, of WO 97/44361 (the publication of PCT/US97/08793).

Accordingly, no new matter has been added by way of these amendments.

Issues under 35 U.S.C. §101 – statutory subject matter

Claim 53 is rejected under 35 U.S.C. §101 as alleged being drawn to non-statutory subject matter. The instant amendment addresses this issue.

Issues under 35 U.S.C. §112, first paragraph, enablement requirement

The rejection under 35 U.S.C. §112, first paragraph, enablement requirement, against claims 1, 2, 4 to 9, 14 to 18, 21 to 22, 24 to 30, 32 to 34, 38 to 52 is maintained and claim 55 is newly rejected.

However, the Office does states that the specification is enabling for an endoglucanase of SEQ ID NO:46, a polynucleotide of SEQ ID NO:45 encoding same, and vectors and host cells comprising the polynucleotide.

Applicants respectfully maintain that the specification enabled the skilled artisan at the time of the invention to identify, and make and use, a genus of polypeptides having endoglucanase or cellulase activity, and the nucleic acids that encode them, to practice the claimed invention – and have provided evidence and expert declaration to support this argument - see Applicants' last response of January 19, 2005, expressly incorporated herein.

The Office maintains, inter alia, that the specification does not provide reasonable enablement for:

- the claimed genus of polynucleotides or polypeptides having 70%, 90%, 95% or 97% sequence identity to an exemplary sequence of the invention; ,
- cellulase polypeptides having 30 or 50 consecutive amino acids of SEQ ID NO:46;
- cellulase polypeptides having 30 or 50 consecutive amino acids of the genus encompassing 70%, 90%, 95% or 97% sequence identity to the exemplary SEQ ID NO:46; or,
- probes comprising 15, 25, 35 or 50 nucleotides of polynucleotide having a 70% sequence identity to SEQ ID NO:45.

The Office repeatedly notes that Applicants are claiming an extremely large genus of polypeptides and polynucleotides (page 7, line 3, of the OA) and to the “great breadth of the claims” (page 5, line 3, of the OA). While Applicants concur that some aspects of the claimed invention encompass broad genera, they also respectfully submit that alternative aspects of the claimed invention encompass a significantly narrower scope, e.g., genera of nucleic acids having 90%, 95% or 97% sequence identity to an exemplary sequence of the invention. For example, claim 18 is drawn to polypeptides having a sequence identity is at least 95% to the exemplary sequence; claim 19 is drawn to nucleic acids that hybridize under stringent conditions to a sequence as set forth in SEQ ID NO:45 having at least at least 97% sequence identity to SEQ ID NO:45; claim 22 is drawn to polypeptides having at least 95% sequence identity to a sequence as set forth in SEQ ID NO:46. Applicants respectfully request the Office recognize the varying scope of each claimed genus and provide independent analysis for each – taking their widely varying scopes into consideration. The scope or breadth of the claims is a significant factor in an enablement determination. In re Wands 8 USPQ2d 1400 (Fed. Cir. 1988), as noted by the Office on page 4, lines 1 to 4, of the OA.

Applicants respectfully maintain that the Office has not met its initial burden of establishing a reasonable basis to question the enablement provided for the claimed invention and have specifically addressed in their previous response how the art used to support the Office’s enablement rejection is not sufficient to rebut the presumptively enabled specification, and rather that repeat these arguments, expressly incorporate their previous response herein. The Office has considered Applicants argument (see, e.g., page 6, lines 17 to 21, and page 7, lines 5 to 10), but has maintained its position that the Office has made a sufficient *prima case* of lack of enablement.

The Office maintains its allegation that it was not routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claims (see, e.g., page 5, lines 11 to 12). In response, an expert declaration by Dr. Jay Short was submitted in Applicants’ last response, where Dr. Short declared, inter alia, that the state of the art at the time of the invention and the level of skill in the art for screening enzymes for endoglucanase/ cellulase activity was very high; procedures for making endoglucanase and cellulase enzyme fragments and sequence variations, e.g., with substitutions, deletions, insertions, and additions, were routine in the art at the

time of the invention; assays for identifying endoglucanase and cellulase enzyme fragments were conventional and routine in the art at the time of the invention; assays for identifying variant polypeptides having endoglucanase and cellulase activity were conventional and routine in the art at the time of the invention; and, use of high through-put screening assays is an example of the high state of art at the time of the invention for screening polypeptides for endoglucanase and cellulase enzyme activity.

The Office has acknowledged that the high level of skill in the art for screening large numbers of potentially active sequence (see, e.g., page 7, lines 11 to 12), and has helpfully emphasized that its greatest concern is the amount of guidance needed in making the genus of claimed variant sequences to satisfy the enablement requirement (page 7, lines 14 to 16). Applicants have addressed this concern with two alternative arguments: first, that specific guidance as to which residues in the exemplary sequence can or cannot be modified to make the claimed genus is not needed because of the high level of skill in the art for screening procedures, e.g., high through-put screening; and second, that in fact the specification and level of knowledge to the skilled artisan at the time of the invention did provide more than sufficient guidance (as to which residues to modify to make the claimed genus). Regarding the first argument, the Office has acknowledged there was a high level of skill in the art for screening large numbers of potentially active sequence (see, e.g., page 7, lines 11 to 12).

However, regarding the second argument as to guidance, the Office maintains its allegation that the specification provides “no guidance with regard to making of variants and mutants or with regard to other uses” (see OA page 5, lines 1 to 3), and “... the lack of guidance, [lack of] working examples (lines 3 to 5, page 5). Applicants respectfully maintain that the specification and level of knowledge to the skilled artisan at the time of the invention did provide more than sufficient guidance to satisfy the enablement requirement.

For example, assays for identifying polypeptides having endoglucanase activity are described in the specification, e.g., on page 17, line 6 to page 18, line 7. Dye-based techniques can be used in cup-plate diffusion assays with excellent sensitivity for the determination of

endoglucanase activity in culture filtrates or during enzyme purification steps (see first paragraph, page 18), as further noted in Example 1, page 36 (see further discussion in Applicants' last response). Also, Dr. Short declared that endoglucanase activity assays also were well known in the art at the time of the invention, e.g., as described in USPNs 4,081,328; 4,904,599; 5,110,735; 5,366,884, to list only a few examples.

Further addressing the Office's concerns regarding guidance as to which residues of the exemplary sequence could or could not be changed to make an enzyme of the invention, in their last response Applicants demonstrated that routine, simple sequence alignment comparison of known endoglucanase and cellulase sequences would have identified regions of identity and dissimilarity to provide guidance to the skilled artisan as to which sequences could be changed, or not changed, to generate structural and/or functional variations of an exemplary endonucleases of the invention, and provided an example of such a sequence alignment. Further guidance regarding endoglucanase structure and active sites was available to the skilled artisan at the time of the invention in the form of three dimensional crystal structures, and Applicants listed a few examples. Thus, if the skilled artisan desired some guidance as to which amino acid residues could be modified to obtain structural or functional variants of an enzyme of the invention, that information was readily available at the time of the invention.

The Office alleges that "[w]ithout such guidance [as to which residues of the exemplary sequence could or could not be changed to make an enzyme of the invention] one of ordinary skill in the art would be reduced to the necessity of producing and testing all of the virtually infinite possibilities." (page 9, lines 7 to 9, of the OA). However, the test for enablement is not that the specification must teach a method(s) for identifying every possible specie of a broad genus. The scope of enablement must only bear a "reasonable correlation" to the scope of the claims. See, e.g., In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). See MPEP §2164.08, pg 2100-197, 8th ed., rev. 2, May 2004. 'The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.' " In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing In re

Angstadt, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). MPEP §2164.06, pg 2100-192, 8th ed., rev. 2, May 2004.

The facts in In re Wands are sufficiently analogous to the instant scenario to help illustrate this point, as explained in the MPEP (§2164.06(b), pg 2100-195, 8th ed., rev. 2, May 2004):

(B) In In re Wands, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), the court reversed the rejection for lack of enablement under 35 U.S.C. 112, first paragraph, concluding that undue experimentation would not be required to practice the invention. The nature of monoclonal antibody technology is such that experiments first involve the entire attempt to make monoclonal hybridomas to determine which ones secrete antibody with the desired characteristics. The court found that the specification provided considerable direction and guidance on how to practice the claimed invention and presented working examples, that all of the methods needed to practice the invention were well known, and that there was a high level of skill in the art at the time the application was filed. Furthermore, the applicant carried out the entire procedure for making a monoclonal antibody against HBsAg three times and each time was successful in producing at least one antibody which fell within the scope of the claims.

In In re Wands, after considering all the factors related to the enablement issue, the court concluded that "it would not require undue experimentation to obtain antibodies needed to practice the claimed invention." Id., 8 USPQ2d at 1407. In In re Wands, it was not necessary to provide a method to routinely identify *every* monoclonal antibody hybridoma made in any particular production round, or every possible monoclonal antibody that could bind the exemplary antigen. Nor was it necessary to produce a working specie after every antibody-making procedure. In fact, in In re Wands, the screening protocols were sufficient to identify (only) at least one antibody after running three procedures. Contrary to the test set forth in In re Wands, the Office erroneously sets a standard for undue experimentation where every possible variant of the exemplary enzyme of this invention is identified. In fact, at the time of the invention it only entailed relatively straightforward and routine protocols to make and identify variants of the exemplary enzyme of this invention. Similarly, determining whether any particular enzyme or nucleic acid fell with the scope of the claimed invention was a very straightforward and routine procedure.

Also analogous to In re Wands, the instant specification provided considerable direction and guidance on how to practice the claimed invention and presented working examples (see discussion above), all of the methods needed to practice the invention were well known and there was a high level of skill in the art at the time the application was filed.

Applicants wish to emphasize that the amount of time needed and the difficulty in screening are not determinative of enablement undue experimentation if the experimentation is routine. Enablement is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive. Atlas Powder Co. v. E.I. Du Pont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984); W.L. Gore and Associates v. Garlock, Inc., 721 F.2d 1540, 1556, 220 USPQ 303, 315 (Fed. Cir. 1983). Experimentation is not considered undue, even if extensive, if it is routine or if the specification provides reasonable guidance regarding the direction of experimentation -- time and difficulty are not determinative of undue experimentation if the experimentation is routine (emphasis added). See PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996); In re Wands, 858 F.2d at 736-40, 8 USPQ2d at 1403-7; Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987) (acknowledging that, because practitioners in that art are prepared to screen large numbers of negatives in order to find a sample that has the desired properties, the screening that would be necessary to make additional antibody species was not “undue experimentation.”). Thus, enablement is not precluded by the necessity to screen large numbers of compositions, as long as that screening is “routine,” i.e., not “undue.”

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue.” As set forth in In re Wands, these factors include, but are not limited to: The breadth of the claims; The nature of the invention; The state of the prior art; The level of one of ordinary skill; The level of predictability in the art; The amount of direction provided by the inventor; The existence of working examples; and, The quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re

Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). MPEP §2164.01(a), pg 2100-185, 186, 8th ed., rev. 2, May 2004. Applicants respectfully aver that taking into consideration all of these factors and all of the evidence and argument presented to the Office, the pending claims are sufficiently enabled by the specification to meet the requirements of 35 U.S.C. §112, first paragraph.

Issues under 35 U.S.C. §112, first paragraph, written description requirement

The rejection of claims 27 to 30 (pages 9 to 11 of the OA), and claims 40 to 43 (pages 14 to 15, of the OA) under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors at the time the application was filed had possession of the claimed invention, is maintained.

Applicants respectfully maintain that the claimed invention is sufficiently described in the specification so that one of ordinary skill in the art would be able to ascertain the scope of the claims with reasonable clarity and recognize that Applicants' were in possession of the claimed invention at the time of filing.

Claims 27 to 30 – enzymatically active subsequences

Pending claims 27 and 28 are directed to polypeptides having endoglucanase or cellulase activity comprising at least 30 or 50 amino acid residues of a polypeptide having at least 70% sequence identity an amino acid sequence as set forth in SEQ ID NO:46. Pending claims 29 and 30 are significantly narrower in scope, being directed to polypeptides having endoglucanase or cellulase activity comprising at least 30 or 50 amino acid residues of a polypeptide having an amino acid sequence as set forth in SEQ ID NO:46. However, claims 27 to 30 do share a common feature (limitation) in that they are drawn to fragments comprising at least 30 or 50 amino acid residues of an exemplary sequence of the invention, and it is this limitation that is the Office's primary concern.

First addressing the issue of whether claims 29 and 30 satisfy the written description requirement, Applicants note that these claims are directed to polypeptides having exactly the same sequence as at least 30 or 50 residues of SEQ ID NO:46, where the claimed fragment has endoglucanase or cellulase activity. Applicants respectfully submit that the sequence of the claimed

proteins that are subsequences of an exemplary sequence of the invention are described with reasonable clarity even though the limitations regarding the length of active subsequences (which at least 30 or 50 residue fragments of SEQ ID NO:46 have activity and fall within the scope of the claim) are not exactly described. The application does not need to describe the claim limitations exactly, but only so clearly that one having ordinary skill in the pertinent art would recognize from the disclosure that Applicants invented and had possession of the claimed subject matter. Whether the specification clearly shows that Applicant was in possession of the claimed invention is not a single, simple determination, but rather is a factual determination reached by considering a number of factors. Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the Applicant was in possession of the claimed species is sufficient. See Regents of the University of California v. Eli Lilly, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); MPEP §2163 II.A.3(a)(i)(C)(2), pg 2100-173, 8th ed., rev. 2, May 2004.

Regarding the enzymatically active polypeptides of claims 29 and 30, which are subsequences of the exemplary enzyme of the invention: the level of skill and knowledge in the art regarding making fragments of a sequence and testing for activity was very high at the time of the invention. The physical and/or chemical properties of the enzymatically active polypeptides of claims 29 and 30, or the actual amino acid sequence, were exactly known with the exception that the exact subsequences are not specifically described. The functional characteristics were described in that all claimed subsequences have endoglucanase or cellulase activity. The method of making the claimed subsequences was well known and routine at the time of the invention. Accordingly, Applicants have disclosed sufficient combination of these identifying characteristics to distinguish the claimed invention from other materials and to lead one of skill in the art to the conclusion that the Applicant was in possession of the claimed species comprising the genera of claims 29 and 30.

Applicants note that claim 1, drawn to polypeptides having endoglucanase or cellulase activity having at least 70% sequence identity to SEQ ID NO:46, or encoded by a nucleic acid having at least 70% sequence identity to SEQ ID NO:45, is not subject to a written description rejection. Claims 27 and 28, as amended, are drawn to polypeptides comprising at least 30 or 50 amino acid residues, respectively, of a polypeptide having at least 70%, 90% or 95% sequence identity an amino acid sequence as set forth in SEQ ID NO:46. Thus, as noted above, the primary issue concerning the Office is whether the claimed subsequences of the exemplary SEQ ID NO:46 are sufficiently described to satisfy section 112, first paragraph.

For reasons analogous to those discussed for claims 29 and 30, above, Applicants respectfully submit that the specification disclosed to the skilled artisan a sufficient combination of identifying characteristics to distinguish the claimed invention from other materials and to lead one of skill in the art to the conclusion that the Applicant was in possession of the claimed species comprising the genera of claims 27 and 28. For example, the genus of enzymatically active subsequences was described by structure, a physico-chemical property and a defined function. Also, as noted above, methods of making the claimed subsequences were well known and routine at the time of the invention. The level of skill and knowledge in the art regarding making fragments of a sequence and testing for activity was very high at the time of the invention. Accordingly, Applicants respectfully submit that the genus of claimed polypeptides of claims 27 and 28 meet the written description requirements of section 112.

Claims 40 to 43 - probes

Claim 40 to 43, as amended, are directed to a genus of probes for identifying or isolated a nucleic acid encoding a polypeptide having endoglucanase or cellulase activity, the probes comprising at least 15, 25, 35 or 50, contiguous nucleotides of a sequence as set forth in claim 32, wherein the probe hybridizes under stringent conditions to a sequence as set forth in SEQ ID NO:45, and the stringent conditions comprise a wash step comprising a wash for 30 minutes at room temperature in a solution comprising 150 mM NaCl, 20 mM Tris hydrochloride, pH 7.8, 1 mM Na₂EDTA, 0.5% SDS, followed by 30 minute wash in fresh solution at T_m-10°C. Claim 32 is drawn to nucleic acids encoding a polypeptide having endoglucanase or cellulase activity and

having a nucleic acid sequence having at least 70% sequence identity to a sequence as set forth in SEQ ID NO:45.

The Office acknowledges that the probes (of set length as 15 or 30 nucleotides) can hybridize to SEQ ID NO:45.

The Office has clarified its concerns – that the claims are drawn to probes “comprising” nucleotides, and that by using this term the claimed composition encompasses unrecited subject matter, and because this unrecited subject matter is not described in the specification, the 112 first paragraph written description rejection was maintained (see the paragraph spanning pages 14 to 15, of the OA).

Applicants respectfully aver that it is not the law that unrecited subject matter in a claim using the opened-ended term “comprising” be described to satisfy the written description rejection of section 112, first paragraph.

Applicants wish to clarify that they use the terms “comprises” or “comprising” as open-ended terms in their well-known, conventional context. The transitional terms “comprising” and “comprises” (and other comparable terms, e.g., “containing,” and “including”) are “open-ended” - they cover the expressly recited subject matter, alone or in combination with unrecited subject matter. See, e.g., Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (“‘Comprising’ is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.”); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) (“comprising” leaves the “claim open for the inclusion of unspecified ingredients even in major amounts”). See also MPEP §2111.03, pg 2100-52, MPEP §2163, section II.A.1., pg 2100-169, 8th ed, Rev. 2, May 2004. See also Invitrogen Corp. v. Biocrest Mfg., 327 F.3d 1364; 66 U.S.P.Q.2D (BNA) 1631, 1634 (Fed. Cir. 2003), describing use of the term “comprises” as an open-ended term. See also Collegenet v. Applyyourself, August 2, 2005, 2005 U.S. App. LEXIS 15805 (“The transitional term ‘comprising’ ... is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.” Georgia-Pacific Corp. v. United States Gypsum Co., 195 F.3d 1322, 1327-28 (Fed. Cir. 1999). “A

drafter uses the term 'comprising' to mean 'I claim at least what follows and potentially "' more. Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc., 212 F.3d 1377, 1383-84 (Fed. Cir. 2000)).

As noted above, Applicants respectfully aver that it is not the law that unrecited subject matter in a claim using the opened-ended term "comprising" be described to satisfy the written description rejection of section 112, first paragraph.

The Office also alleges that the specification does not contain any disclosure of the function of all DNA sequences encompassed by the claim. The instant amendment addresses this issue – the amended claims are drawn to probes capable of identifying or isolating nucleic acids encoding a polypeptide having endoglucanase or cellulase activity.

Accordingly, Applicants respectfully submit that the pending claims 40 to 43 meet the written description requirement under 35 U.S.C. §112, first paragraph.

Issues under 35 U.S.C. §101 – double patenting

Claim 36 is rejected under 35 U.S.C. §101, as allegedly claiming the same invention as that of claim 11 of USPN 5,789,228.

Claim 11 of USPN 5,789,228, reads: "An isolated polynucleotide selected from the group consisting of: a) SEQ ID NO:1; b) SEQ ID NO:1 wherein T can also be U; c) nucleic acid sequences complementary to a) and b); and d) polynucleotides contained in ATCC deposit No. 97516 and which encode the amino acid sequence of SEQ ID NO:2."

The instant amendment addresses this issue. Claim 36 of the instant applications as amended reads "The isolated or recombinant nucleic acid of claim 35, wherein the nucleic acid sequence has a sequence as set forth in SEQ ID NO:45 or encodes an amino acid sequence as set forth in SEQ ID NO:46." After entry of the instant amendment, the scope of the two claims clearly differ, and the rejection under section 101 can be properly withdrawn.

Obviousness-like double patenting

Claims 2, 4, 5 to 9, 14, 32 to 43 and 53, stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1 to 11 of U.S. Patent No. (USPN) 5,789,228, because – although they are not identical – they are not patentably distinct from each other (see page 16, of the OA).

It is alleged that SEQ ID NO:45 of the instant application is 100% identical to SEQ ID NO:1 of USPN 5,789,228. However, attached herein is a direct sequence comparison of these two sequences, and they clearly are not identical. These two sequences share only about 44% sequence identity.

Additionally, the Office mentions a previous Office Action showing that SEQ ID NO:45 of the instant application is 100% identical to SEQ ID NO:1 of USPN 5,789,228. Applicants respectfully note that in the first Office Action on the merits mailed July 22, 2004, at least in the version they received, did not include such a sequence comparison.

Accordingly, because SEQ ID NO:45 of the instant application is not 100% identical to SEQ ID NO:1 of USPN 5,789,228, are different sequences, the provisional rejection under the judicially created doctrine of obviousness-type double patenting can be properly withdrawn.

CONCLUSION

In view of the foregoing amendment and remarks, Applicants respectfully aver that the Examiner can properly withdraw the rejection of the pending claims under 35 U.S.C. §112, first paragraph, 35 U.S.C. §101, and the provisional rejection under the judicially created doctrine of obviousness-type double patenting. In view of the above, claims in this application after entry of the instant amendment are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 564462000502. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

As noted above, Applicants have requested a telephone conference with the undersigned representative to expedite prosecution of this application. After the Examiner has reviewed the instant response and amendment, please telephone the undersigned at 858 7205133.

Dated: October 13, 2005

Respectfully submitted,

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